

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION AT COLUMBUS

ORGANIC TRADE ASSOCIATION,

Plaintiff,

vs.

ROBERT J. BOGGS, solely in his official
capacity as Ohio Director of Agriculture,

Defendant.

INTERNATIONAL DAIRY FOODS
ASSOCIATION,

Plaintiff,

vs.

ROBERT J. BOGGS, solely in his official
capacity as Ohio Director of Agriculture,

Defendant.

) Case Nos. 2:08-CV-628, 629

) Honorable James L. Graham
) Magistrate Judge Norah McCann King

) **ORGANIC TRADE ASSOCIATION'S**
) **REPLY IN SUPPORT OF ITS MOTION**
) **FOR SUMMARY JUDGMENT AND IN**
) **OPPOSITION TO DEFENDANT'S**
) **MOTION FOR SUMMARY JUDGMENT**

) Date Action Filed: June 30, 2008

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The Director argues that the Ohio Rule is not preempted because “[s]tate laws designed to protect consumers, including food-labeling laws, ‘represent an exercise of the historic police powers of the States and thus are not preempted ‘in the absence of an unambiguous congressional mandate to that effect.’” There is no dispute that Ohio has broad police powers that can be used to protect consumers. Those police powers, however, are not unfettered and, when in conflict with a federal enactment, must give way.

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Even where Congress has not occupied the field of regulation in a given area, a state law is preempted when it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. See also Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 965 (6th Cir. 2004). The Ohio Rule is preempted because it is such an obstacle. The express, statutorily prescribed purposes of OFPA include the establishment of “national standards governing the marketing of certain agricultural products as organically produced products,” “to assure consumers that organically produced products met a consistent standard” and “to facilitate interstate commerce in fresh and processed food that is organically produced.” 7 U.S.C. § 6501. The Ohio Rule stands as an obstacle to the achievement of these congressionally mandated objectives by requiring organic dairy operators to exclude particular language related to the organic characteristics of their products from their labels, *i.e.*, the lack of growth promoting or production increasing hormones, pesticides, and antibiotics.

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Preemption operates to invalidate a state law where a scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress “left no room” for supplementary state regulation. Gade v. Nat’l Solid Wastes Management Ass’n, 505 U.S. 88, 98 (1992). The labeling requirements in OFPA are comprehensive, explicit, detailed and occupy the entire field of regulation. The Director contends, however, that such a sweeping regulatory scheme does not prevent Ohio from enacting laws regarding “false or misleading labeling of dairy products.” The Director’s assertion simultaneously recognizes that OFPA is an exhaustive regulatory scheme which standardizes regulation of organic product labeling on a federal level and confuses the issue of precisely what OTA argues is preempted by that federal law. OTA contends that OFPA occupies the entire field of regulation concerning the labeling of

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i. The Director Has Produced No Evidence that Absence Labels Are False and Misleading..... 11

The Director has provided no evidence that the dairy product labels that are now regulated under the Ohio Rule are, or potentially are, misleading. First, the Director produced virtually no documents to OTA indicating that there were consumer complaints or confusion over dairy product labeling. Second, in support of his opposition brief, the Director provided no documents, evidence or affidavits which indicate that absence labels are false and misleading. Finally, during the depositions of the Director and Mr. Jones each conceded that prior to enacting the Rule there was no evidence that plaintiff’s members’ labels were false and misleading.

a. The Composition Claims on OTA’s Members’ Labels are Not False and Misleading..... 12

The Director, in his opposition brief, provides just one justification for the outright ban on composition claims such as “No rbST” and “No Artificial Growth Hormones.” The Director argues that it is constitutionally permissible to flatly prohibit such composition claims because “composition claims regarding rbST and kindred compounds are *impossible* to verify.” Under the strict guidelines of OFPA and NOP, organic dairy farmers and processors, by law, may not use artificial growth hormones, antibiotics or toxic pesticides on their herds. Both Boggs and Jones testified that the only way rbST could be present in a dairy product is if the cows producing the milk were treated with rbST. Thus, it is an indisputable fact that if a dairy farmer has gone through the rigors of becoming certified organic, the dairy products produced by that farmer do not contain rbST. As the ability or inability to verify the non-use claims is the Director’s only justification for banning composition claims such as “No rBST, there can be no argument that, *for organic companies*, such composition claims are false and misleading. The Ohio Rule also bans other kinds of composition claims such as “No Pesticides” and “No Antibiotics.” The Director argues that such claims are inherently misleading because “while presumably true, such claims ... create a false impression that a competitor’s dairy products not so labeled might contain such prohibited compounds.” The organic dairy industry operates under a very specific set of rules and regulations that require that no cows be treated with antibiotics and no pesticides be used on any feed product. The Director has not established that such claims are false and misleading and thus he must show that the Ohio Rule directly and materially advances a substantial governmental interest that is no more extensive than necessary to achieve his goals.

b. The Production Claims are Not False and Misleading..... 15

The Ohio Rule states that a dairy label may contain a production claim that “this milk is from cows not supplemented with rbST” so long as it also contains a

contiguous disclaimer conforming to the Ohio Rule's requirements as to acceptable wording, placement, font, style, case, size and color. Even under Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985) the court still must evaluate whether the speech at issue was inherently or potentially misleading. Further, the Supreme Court's decision in Ibanez v. Florida Dept. of Business and Prof. Regulation, Board of Accountancy, 512 U.S. 136, 146 (1994), decided after Zauderer, stated that "If the 'protections afforded commercial speech are to retain their force,' we cannot allow rote invocation of the words 'potentially misleading' to supplant the Board's burden to 'demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.'" The Director has not come forward with the necessary evidence to meet his burden.

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Ibanez makes clear that the Director must still satisfy the multi-prong test in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557 (1980). See also Mason v. Florida Bar, 208 F.3d 952 (11th Cir. 2000).

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OTA does not quarrel with the Director's assertion that Ohio has a substantial interest in ensuring the accuracy of consumer information and in preventing consumers from being misled regarding the products they consume. However, the Director must do more than just show that it has a substantial interest; it must also demonstrate that the Rule *achieves* that substantial government interest. Central Hudson, 447 U.S. at 566. The Director has entirely failed to meet his burden.

b. The Restriction Does Not Directly and Materially Advance the State Interest 21

Central Hudson requires the Director to show that the Ohio Rule directly and materially advances the state interest. The Director, under this prong, must "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." Edenfield v. Fane, 507 U.S. 761, 770-771 (1993). Requiring the disclosure of even truthful claims is not constitutional where the Director has failed to establish any harm.

c. There is Not a Reasonable Fit Between the Government's Goals and the Means Chosen to Accomplish Them 22

The final prong of the Central Hudson test requires that the Court determine whether there is a "reasonable fit" between the government's goals and the means chosen to accomplish them – a means that is "narrowly tailored" to achieve the desired objective. Director Boggs' own testimony establishes that there were "obvious less-burdensome

alternatives” to the Rule ultimately enacted by the Director. Florida Bar v. Went For It, Inc., 515 U.S. 618, 632 (1995). The FDA guidance is far less restrictive and the record is replete with evidence of states that have chosen to pass laws regulating dairy labels which are much less restrictive than Ohio’s rule.

- C. The Ohio Rule is Unconstitutionally Void For Vagueness Because it Fails to Clearly Describe the Language it Prohibits and Provides Unbridled Discretion for Enforcement in the Ohio Department of Agriculture24

The Director argues that the Ohio Rule is not unconstitutionally void for vagueness based upon the general principal that “when a law is susceptible of more than one permissive construction, courts must ‘construe the [law] to avoid [constitutional] problems’ if it is ‘fairly possible.’” The Director next argues that where public interests are involved, the word “may” actually means “shall.” This argument is not supported by any relevant case law or by basic common sense. Ordinary textual analysis, and reference to a dictionary definition of the word may, demonstrates that “may” does not have the same meaning as “will” or “shall.” Further, Defendant’s Opposition does not address, in any manner, the cases cited in OTA’s motion for the proposition that courts apply heightened scrutiny when determining the constitutionality of potentially vague statutes that implicate First Amendment rights, conceding that, in the context of such statutes “an enactment . . . may withstand facial constitutional scrutiny only if it incorporates a high level of definiteness.” Belle Maer Harbor v. Charter Township of Harrison, 170 F.3d 553, 557 (6th Cir. 1999).

- D. The Ohio Rule Violates the Dormant Commerce Clause of the United States Constitution26

For purposes of brevity, OTA incorporates by reference the arguments made by IDFA in its Reply brief filed concurrently herewith and the declarations and Separate Statement of Undisputed Facts submitted by OTA in support of its Motion for Summary Judgment.

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I. INTRODUCTION

A certified organic cow is never given any artificial growth hormones. This fact is verified by a United States Department of Agriculture-accredited certifier, who is audited and overseen by the USDA's National Organic Program. The certified organic marketers of the certified organic milk produced by these cows put the USDA Organic Seal on their cartons, along with statements like "No Synthetic Hormones" or "Produced without Synthetic Hormones." According to the Ohio Department of Agriculture, however, these statements are misleading. This assessment is based on nothing more than the opinions of the Ohio Director of Agriculture, Robert J. Boggs and his staff. Indeed, statements like "No Synthetic Hormones" have been deemed so misleading, that they are absolutely forbidden in the state of Ohio, and the statement "Produced Without Synthetic Hormones" must now be accompanied by a disclaimer, in a particular size, font, style, case and color. Failure to comply with this regulation could result in product being pulled off Ohio supermarket shelves. Yet, according to Director Boggs, this regulation is merely a clarification of the FDA guidance which has been assisting the dairy industry for nearly fourteen years. This clarification, vaguely written, restricting free speech, interfering with the Organic Foods Production Act, causing upheaval for the dairy industry, and impinging on consumers' right to know about the products they purchase, is much more than just a "clarification", and must be overturned by this court.

The organic dairy industry is regulated under the Organic Foods Production Act and the National Organic Program, a Federal regulatory regime made up of 20 statutes and over 600 regulations (collectively "OFPA"). OFPA regulates literally every aspect of organic dairy farming, from the quality of land to be used, to the qualifications of the certifying agents, to the labels that can be affixed to organic products. In passing OFPA, Congress set forth several clear objectives the Act was designed to meet: among those were "to assure consumers that organically produced products met a consistent standard" and "to facilitate interstate commerce in fresh and processed food that is organically produced." 7 U.S.C. § 6501. Indeed, Congress made clear that "[t]he organic industry is encouraged to inform consumers about all materials used in organic production." S.R. Rep. No. 101-357 at 300 (1990).

The Ohio Rule, by restricting organic dairy processors ability to make statements about their production practices, would actually prevent the organic industry in Ohio from furthering OFPA's objectives. Moreover, the Ohio Rule attempts to regulate in a field fully occupied by the federal government and stands as a direct obstacle to the accomplishment of certain federal objectives and it is, therefore, completely preempted.

Ignoring federal preemption and relying on Ohio's police powers to purportedly protect Ohio consumers from false and misleading information, the Director enacted a rule, which in purpose and effect, actually *limits* the truthful information that organic dairy processors may provide to Ohio consumers. In support of the rule, the Director argues – without any basis – that certain statements on dairy labels are, or perhaps have the potential to be, false and misleading. Despite being given at least two opportunities to provide written evidence or deposition testimony, the Director has provided *no* evidence that consumers have been or could be misled and *no* evidence that the claims made on plaintiff's members' dairy labels are false. Simply put, the rule is based on a faulty determination, which is premised on little more than unsupported conjecture, and must be declared unconstitutional.

The Director has now essentially admitted that the Ohio Rule violates plaintiffs' members' First Amendment commercial free speech rights. The testimony of the Director and the Chief of the ODA's Dairy Division, as well as the briefs filed in this action, make plain that the Director had little more than his and his staff's opinions on the matter to support the Rule. Indeed, the Director admitted that there was no evidence of any consumers being misled prior to enactment of the Rule. The Director testified "I was aware of the rbST issue in that it was a controversial product, but not in regard or relationship to any labeling." (Deposition of Robert J. Boggs ("Boggs Depo.") at 8:22-24). The Director's speculation on this matter is insufficient. The Supreme Court held that the "free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful." Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 646 (1985). The Director has failed to meet this burden.

Thus, with no evidence that any label actually misled any Ohio consumers, the Director enacted a Rule that bans completely “composition” claims such as “No rbST” and “No Artificial Hormones” on the ground that those claims are “impossible” to verify. The Director’s justification, however, completely ignores the extensive regulation under which all organic dairy processors operate which mandate *and verify that no certified organic cows may ever be treated with* any artificial growth hormone, including rbST. Therefore, at least as to the organic industry, the Director’s justification for his outright ban on “composition” claims is completely unsupportable.

In addition, and without evidence of any consumer being misled, the Rule places unnecessarily excessive burdens on the use of “production” claims such as “this milk is from cows not supplemented with rbST.” As shown below, not only are the burdens imposed by the Rule unconstitutional, they also undermine one of the Director’s claimed objectives in enacting the Rule. The Director testified, “[t]he purpose of the rule is to make sure that the consumers of Ohio have the most accurate, complete, and balanced information concerning dairy products.” (Boggs Depo. at 56:14-17). The Rule, however, will have the opposite effect. In order to avoid running afoul of the Ohio Rule and its strict requirements, dairy processors will likely remove information about the use or non-use of rbST from their labels, depriving Ohio consumers of information which even the Director believes they want. Accordingly, the Ohio Rule impermissibly restricts speech which is not false or misleading and which does not even have the potential to be misleading and, in fact, undermines the Director’s own stated objectives.¹

Finally, the Ohio Rule violates the dormant Commerce Clause of the United States Constitution, which forbids individual states from projecting their regulatory regime into other states. The practical effect of the Ohio Rule is to mandate what dairy processors in other states can and cannot affix to their labels. According to the Director he was aware that it would be

¹ Relying on an obscure quote from the Corpus Juris Secundum, the Director argues that the use of the word “may” in the Ohio Rule does not render the Rule void for vagueness because, in the context of the Ohio Rule, “may” actually means “shall.” As will be addressed more fully below, the Director’s strained argument has no merit

“very expensive” for national brands “to have a set of labels only for Ohio and a different set for the rest of the country.” In response to that concern, the Director advised the national brands that they could use the Ohio label throughout the country. (Boggs Depo. at 65:20-66:2). Thus, the Director gave national dairy processors a “choice”: either spend the money to have an Ohio-only set of labels, change all labels throughout the country to conform to Ohio, or do not sell milk in Ohio at all. This is hardly a real choice, and demonstrates Ohio’s violation of the dormant Commerce Clause. The Director’s “choice” also ignores the likelihood that other states might require their own changes to the Ohio language, thus creating a web of mutually exclusive label regulations that will effectively bar the marketing of organic milk in certain of these states.

II. ARGUMENT

A. The Ohio Rule is Preempted by OFPA Because it Requires Organic Dairy Operators to Comply With Labeling Requirements Which are Inconsistent With Federal Law

The Director argues that the Ohio Rule is not preempted because “[s]tate laws designed to protect consumers, including food-labeling laws, ‘represent an exercise of the historic police powers of the States’ and thus are not preempted ‘in the absence of an unambiguous congressional mandate to that effect.’” (Opposition at 28). There is no dispute that Ohio has broad police powers that can be used to protect consumers. Those police powers, however, are not unfettered and, when in conflict with a federal enactment, must give way.

i. The Ohio Rule is Preempted Because it Stands as an Obstacle to the Achievement of the Purposes of OFPA

A state law is preempted when it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 965 (6th Cir. 2004). The Director argues that the Ohio Rule is not preempted because “the [Ohio] Rule does not prohibit organic labeling that OFPA compels;” in other words, because compliance with the Ohio Rule and OFPA is not physically impossible, the Ohio Rule is not preempted. (Opposition at 33). The Director’s argument is unavailing because physical impossibility of compliance with both state and federal law is not a requirement for a court to find the existence of obstacle preemption. Indeed, the court in Motor Vehicle Mfrs. Ass’n of the

U.S., Inc. v. Abrams, 899 F.2d 1315, 1322 (2d Cir. 1990), cited by the Director, recognized that conflict and obstacle preemption are separate theories upon which preemption may be found. As discussed below, the Ohio Rule is preempted because it “stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress,” not because compliance with both is physically impossible. Gade v. Nat’l Solid Wastes Management Assn’, 5 U.S. 88, 98 (1992)

One of the express, statutorily prescribed purposes of OFPA is the establishment of “national standards governing the marketing of certain agricultural products as organically produced products.” 7 U.S.C. § 6501. OFPA was also intended by Congress “to assure consumers that organically produced products met a consistent standard” and “to facilitate interstate commerce in fresh and processed food that is organically produced.” *Id.* The Ohio Rule stands as an obstacle to the achievement of these congressionally mandated objectives by requiring organic dairy operators to exclude particular language related to the organic characteristics of their products. Specifically, that organic dairy cows are *never* treated with artificial growth hormones and therefore milk from those cows can not possibly contain artificial growth hormones.

By prohibiting distributors of organic dairy products from using their product labels to highlight the production processes that make their products organic, *i.e.*, the lack of growth promoting or production increasing hormones, pesticides, and antibiotics, the Ohio Rule is an obstacle to the establishment of national standards for the marketing of organic dairy products and assuring consumers that organically produced products meet a consistent standard. Gade, 505 U.S. at 98.² The Ohio Rule sets forth unique labeling standards that apply to all organic dairy products sold in Ohio. Those labeling standards are not required in other state. The net

² OFPA’s legislative history further supports OTA’s position that the Ohio Rule undermines Congress’s intent in passing the OFPA. S.R. Rep. No. 101-357 at 300 (1990) (“The organic industry is encouraged to inform consumers about all materials used in organic production); See also 136 Cong. Rec. 18,197 (1990) (“If consumers . . . prefer organically produced foods, it must be clear to them and to farmers . . . what constitutes organically grown foods.”); 135 Cong. Rec. 29,411 (1989) (“Organic certification standards should be national in scope, touch and fully enforced.”).

effect of the Rule is to subject national organic dairy processors to conflicting product labeling standards throughout the country. Consequently, the Ohio Rule is preempted by OFPA because it prevents OTA members from engaging in a national standard for the marketing of their organic products and from assuring their customers that their product meets consistent, nationwide standards.

Nevertheless, the Director, in conclusory terms, argues that the Ohio Rule does not obstruct Congress' purpose in passing OFPA because "the Rule in no way prohibits or interferes with organic producers' compliance with livestock handling requirements" and "there is no evidence that national organic marketing standards are intended to preclude states from protecting consumers from false and misleading dairy labeling . . ." (Opposition at 33-34). The Director makes no further argument in support of his position. OTA concedes that the Ohio Rule does not prohibit organic producers from complying with OFPA's livestock handling requirements. OTA did not advance that theory in its motion and it is entirely unclear how such an argument rebuts the contention that the labeling requirements imposed by the Ohio Rule present an obstacle to the accomplishment of OFPA's objectives. Regardless, it is beyond dispute that the linguistic prohibitions forced upon organic dairy operators by the Ohio Rule will prevent them from conveying to their customers that their products conform to the federal regulations that they must comply with in order to become certified organic. For example, although organic operators are not allowed to use rbST or rbGH on their dairy cows, the Ohio Rule places extreme limitations on the ability of the operators to convey that information to their consumers. Further, organic dairy operators are entirely prohibited by the Ohio Rule from conveying to their consumers that they do not use pesticides or antibiotics in the production of their organic products. By placing such limitations on the labels of organic dairy products sold in Ohio, the Ohio Rule serves as an obstacle to the achievement of the express Congressional purpose in passing OFPA, and is therefore preempted.

**ii. The Organic Food Production Act and the National Organic Program
Occupy the Field of Regulation for Labeling of Organic Products**

Preemption operates to invalidate a state law where a scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress “left no room” for supplementary state regulation. Gade, 505 U.S. at 98. OFPA’s labeling regulations are comprehensive, explicit, detailed and occupy the entire field of regulation. As more fully described in OTA’s opening brief, OFPA is made up of over 20 statutes and well over 600 regulations. (Organic Trade Association’s Motion for Summary Judgment at 11-20).³

In the face of such extensive regulation, the Director concedes, as he must, that “OFPA and NOP may show that Congress has extensively regulated the field of organic labeling.” (Opposition at 29). The Director contends, however, that OFPA’s sweeping regulatory scheme does not prevent Ohio from enacting laws regarding “false or misleading labeling of dairy products.” (Id.). The Director’s assertion simultaneously recognizes that OFPA is an exhaustive regulatory scheme, which standardizes regulation of organic product labeling on a federal level, and confuses the issue of precisely what OTA argues is preempted by that federal law. OTA does not contend that OFPA prevents Ohio from passing any law regarding false and misleading food labeling generally; rather, OTA contends that OFPA occupies the entire field of regulation concerning certified organic products.

The Director claims that the Ohio Rule “does not purport to, or effectively, regulate organic labeling of agricultural products.” (Opposition at 31). The Director supports this contention by arguing that the Ohio Rule does not “run afoul of the OFPA because it does not

³ OFPA regulates the quality of land a farm can operate on, the length of time livestock needs to live on an organic farming operation to be considered “organic,” livestock living conditions, the health care to be given to livestock, the type and quality of feed that can be given to livestock, as well as a prohibition on the use of certain substances like artificial growth promoting hormones, antibiotics and toxic pesticides. (OTA’s Motion for Summary Judgment at 14). In addition, organic dairy operations need to file specific and comprehensive documents with United States Department of Agriculture in order to become certified organic and there are regular inspections of certified organic farming operations by highly trained, independent, third party certifying agents. 7 U.S.C. §§ 6514-6516. Violations of OFPA are subject to a penalty of \$10,000, per violation. 7 U.S.C. § 6519.

prohibit organic producers and handlers from informing consumers about materials used in organic production – only from adding gratuitous statements about hormones not used in production.” (Id.). The Director’s admission that the Ohio rule prevents organic operators from disclosing to consumers the compounds *not present* in their organic products, however, concedes that the Ohio Rule effectively regulates labeling of organic agricultural products. This is obviously the case because many of the very production processes mandated by federal law, which make a product organic in the first place, concern compounds which may *not be used* in organic production. See e.g., 7 C.F.R. § 205.237 (regarding the prohibition on providing hormones to livestock to promote growth); 7 U.S.C. § 6504 (regarding the prohibition on the use of synthetic chemicals). Indeed, the primary distinguishing characteristic of organic products is that they *do not* contain certain things (such as growth promoting hormones) that traditional agricultural products do contain. The Ohio Rule clearly regulates labeling of organic agricultural products by prohibiting organic operators from disseminating information to consumers regarding the production practices that make their products certified organic under federal law.

The Director relies on Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963), to support his argument that OFPA does not represent an “unambiguous congressional” mandate to regulate the field of organic labeling. The issue facing the Paul court was whether a California statute, which prohibited the transportation or sale in California of avocados containing less than 8% oil by weight, was preempted by federal regulations regarding avocado maturity issued under the Federal Agricultural Marketing Agreement Act of 1937 (“FAMA”). Id. at 133. The Court found that the California statute was not preempted because nothing in FAMA disclosed an intent to create a comprehensive scheme of federal regulation. Id. at 147.

In its ruling, the Paul court compared FAMA with another federal law, the Federal Tobacco Inspection Act (“FTIA”), which the court had previously determined *did* preempt contradictory state laws. The Court stated that FTIA preempted conflicting state laws even though FAMA did not because, with respect to FTIA, “Congress had declared ‘uniform standards of classification and inspection’ to be ‘imperative for the protection of producers and others engaged in commerce and the public interest therein.’” Id.

OFPA is analogous to FTIA. Like FTIA, which had preemptive effect, OFPA was passed with the intent to create uniform standards of classification and inspection of organic agricultural products. Specifically, OFPA was designed to: (1) to establish national standards governing the marketing of certain agricultural products as organically produced products; (2) to assure consumers that organically produced products met a consistent standard; and (3) to facilitate interstate commerce in fresh and processed food that is organically produced. 7 U.S.C. § 6501. Congress' intent to create uniform standards is borne out by the detailed and extensive regulations passed under OFPA which were summarized above and in OTA's opening brief. Rather than aid the Director's argument, Paul reinforces OTA's position that OFPA preempts the Ohio Rule.⁴

Finally, the Director's contention that Ohio does not need to have a state organic program approved by the Secretary of Agriculture in accordance with 7 C.F.R. § 205.620(a) in order to place regulations on the labeling of organic products is fallacious. The Director supports this proposition by contending that "NOP restrictions do not require states to obtain such approval in order to regulate false or misleading dairy labeling." (Opposition at 32). The Director's assertion confuses precisely what types of laws Ohio is prohibited from enacting due to the comprehensive regulatory scheme set forth by OFPA. OTA does not contend that OFPA preempts state laws concerning false or misleading labels. As explained above, the Ohio Rule does not "simply prohibit additional false or misleading information . . . or require additional

⁴ The Director's reliance on Partlo v. Johanns, 2006 U.S. Dist. LEXIS 43071 (D.D.C. June 11, 2006), for the proposition that "by themselves, the OFPA and NOP simply establish a certification program for organic products" is misplaced. (Opposition at 30). The Partlo court was faced with the question of whether OFPA and NOP created emergency or other financial support for organic agricultural producers. Partlo, 2006 U.S. Dist. LEXIS at *26. The court held that the actual extent of the regulation created by OFPA and NOP was unrelated to emergency and financial support for organic agricultural producers and dismissed the case. Partlo, 2006 U.S. Dist. LEXIS at *26. Partlo is easily distinguishable from the instant case. Here the issue for determination is whether Ohio can pass a regulation which dictates what organic processors may or may not put on their labels. It is uncontroverted that the labeling of organic products is specifically and extensively regulated by OFPA. This is entirely unlike the situation in Partlo where the issue of emergency or financial support had not been addressed at all in any OFPA statute or NOP regulation.

information;” rather, the Ohio Rule prohibits organic dairy processors from including information on their labels which conveys to consumers the practices which make their products organic in the first place.

B. The Ohio Rule Impermissibly Impinges on OTA’s First Amendment Commercial Free Speech Rights⁵

i. The Director Has Produced No Evidence that Absence Labels Are False and Misleading

The Director has put forth several contradictory justifications in support of the Ohio Rule. In press releases and articles issued concurrently with the Rule, the Director stated that the Rule was necessary to ensure that consumers received only the most “accurate and balanced information.” (SSUF ¶ 42). Later, perhaps realizing that the law requires the Director to show that the regulated labels were or potentially were false and misleading, the Director claimed, in his opposition brief, that the Rule was necessary “to ensure that Ohio consumers receive truthful and non-misleading information regarding the dairy products that they consume.” (Opposition at 4). The Director’s shifting justifications for the Rule highlights the now undeniable fact that the Director has not produced any evidence that consumers were or potentially were misled by absence labels used in Ohio

Without any evidence of harm to Ohio consumers, the Director’s real justifications are laid bare. Prior to enactment of the Rule, Ohio consumers began to demand milk products that had not been treated with rbST. This increase in consumer demand negatively effected dairy processors who chose to use rbST on their herds, as well as the company that produces and manufacturers rbST, Monsanto. Thus, the evidence that the Director had prior to enacting the Rule did not indicate that consumers were misled, instead it revealed that processors who used rbST were not able to compete as well as they once could. It cannot be disputed that protecting

⁵ In an effort to avoid unnecessary duplication, and given that there are some overlapping arguments made by OTA and IDFA regarding the Ohio Rule’s violations of the first amendment, OTA incorporates by reference all of the arguments made in IDFA’s brief as if fully set forth herein, what follows are arguments specific to OTA.

Ohio dairy processors from the demands of the national marketplace simply *cannot* justify limiting the commercial free speech rights of processors who choose not to use rbST.

Regardless of the Director's stated justifications for the Rule, there is no doubt that the Director has not demonstrated that the dairy product labels that are now regulated under the Ohio Rule are, or potentially are, misleading.

a. The Composition Claims on OTA's Members' Labels are Not False and Misleading

In his opposition, the Director argues that the Ohio Rule draws a distinction between "composition" and "production" claims. The Director, in his opposition brief, provides just one justification for the outright ban on composition claims such as "No rbST" and "No Artificial Growth Hormones." The Director argues that it is constitutionally permissible to flatly prohibit such composition claims because "composition claims regarding rbST and kindred compounds are *impossible* to verify." (Opposition at 6, emphasis in original). This fact, the Director asserts, "creates an unacceptable risk of misleading consumers regarding the content of the dairy products they consume." (*Id.*) By this argument, the Director lays bare one of the primary inadequacies of the Ohio Rule and, indeed, the Director's arguments in support of the Rule as a whole. Specifically, the Director ignores, entirely, the incontrovertible fact that organic dairy farmers and processors stand in a fundamentally different position than traditional dairy farmers and processors. Simply stated, the justification for the outright ban of "composition" claims provided by the Director, does not apply to the organic industry.

As an initial matter, the Director's complete ban on "composition" claims constitutes a prophylactic ban on speech which is generally disfavored by the courts. Supreme Court precedent dealing with prophylactic bans reveals that the Court has only sanctioned such bans in two limited circumstances: (1) if there is history of actual deception and abuse worked upon the public (*In re R.M.J.*, 455 U.S. 191 (1982)); and (2) if the speech at issue is inherently misleading. (*Zauderer*, 471 U.S. at 641, 644.

The Director has failed to produce any evidence establishing that “composition” claims are actually misleading. Indeed, prior to enacting the Rule, the Director received no complaints that dairy labels were misleading. See e.g., Boggs Depo. at 27:17-23 (“Q: ... Prior to the public meetings that you instituted regarding rbST labeling ... you [were] not aware of any consumer complaints about rbST labeling?” A: I am not personally aware of any before October of 2007.”); Deposition of Lewis Jones (“Jones Depo.”) at 9:6-10:7 (“Q: It’s possible you had [no emails that commented adversely about rbST labeling on milk products] before October 22nd of ’07; is that correct? A: Possibly we had not. That’s possible.”). Indeed, OTA established in its Separate Statement of Undisputed Facts that there was no evidence of consumer deception. These undisputed facts remain uncontroverted by the Director and must be taken as true by this Court. There being no evidence that “composition” claims are actually misleading, the Director argues that such claims have the potential to be misleading because they are “impossible to verify.”

Under the strict guidelines of OFPA, organic dairy processors may not, by law, use artificial growth hormones, antibiotics or toxic pesticides on their herds. Moreover, organic dairy farmers and processors are subject to continual oversight by the federal government and subject to steep fines for violations of OFPA and NOP. (See Section II.A, *supra*). Both Boggs and Jones confirmed that organic dairy operations may not use rbST. Boggs testified, “Q: ... Isn’t it true that for organic dairy farmers, the nonuse of rbST is demonstrably true and verifiable? ... A: Yes.” (Boggs Depo. at 72:10-14). Jones testified, “Q: ... Isn’t it correct that certified organic farmers are required to verify that they do not use rbST? A: That has been added, yes, to their qualifications, yes.” (Jones Depo. at 29:15-19). Both Boggs and Jones testified that the only way rbST could be present in a dairy product is for the cows producing the milk to have been treated with rbST. (Boggs Depo. at 84:8-85:4; Jones Depo. at 29:8-14). Thus it is an indisputable fact that if a dairy farmer has gone through the rigors of becoming certified organic, the dairy products produced by that farmer do not contain rbST.

Having gone through the years-long process of becoming certified organic, during which the OFPA commands that a farmer must not apply any fertilizers, pesticides or other chemical

products proscribed under OFPA to his or her fields and pastures for a full three years, and that the farmer must not use any antibiotics, hormones or other health aids proscribed under OFPA to his or her cows for at least a full year, and after being subject to strict oversight by the federal government to ensure compliance with OFPA and NOP, Ohio is now telling organic dairy processors that they have still not done enough and that their non-use of rbST is still “impossible to verify.” The Director is effectively telling the organic industry that compliance with strict federal regulations is not good enough to assure the Director that “No rbST” claims on organic dairy labels are actually true and, indeed, could not possibly be misleading. Compliance with strict federal regulations must trump the Director’s unsupported assertions that composition claims are “impossible to verify.” There can be little room for doubt that, *for organic companies*, composition claims are demonstrably true and not misleading.

The Ohio Rule also bans other kinds of composition claims such as “No Pesticides” and “No Antibiotics.” The Director argues that such claims are inherently misleading because “while presumably true, such claims ... create a false impression that a competitor’s dairy products not so labeled might contain such prohibited compounds.” (Opposition at 6-7). The Director supports his argument not with evidence that consumers have actually been misled by such claims, because there is none, or with analogous case law, because none exists, but instead with a strained hypothetical, analogizing claims regarding pesticides and antibiotics to an imaginary claim that milk is “radiation free.” The Director’s hypothetical has no applicability to this case. The organic dairy industry operates under a very specific set of rules and regulations that require that no cows be treated with antibiotics and no pesticides be used on any feed product. The Director presents no factual or legal arguments, nor can he, that support the novel proposition that a dairy processor may not inform its consumers of the production practices of that processor. The Director has not established that such claims are false and misleading and the outright ban on those statements is without support.

b. The Production Claims are Not False and Misleading

The Ohio Rule states that a dairy label may contain a production claim that “this milk is from cows not supplemented with rbST” so long as it also contains a contiguous disclaimer

conforming to the Ohio Rule's requirements as to acceptable wording, placement, font, style, case, size and color. The Director argues that OTA has put forward the wrong standard for the analysis of the Ohio Rule's constitutionality under the First Amendment. According to the Director, because this portion of the Ohio Rule does not ban speech and merely requires the inclusion of a disclaimer, he must only satisfy a lower reasonableness standard under Zauderer, 471 U.S. 626. (Opposition at 7-8).

The Director's extensive quotation of the purported standard set forth in Zauderer does not provide a complete representation of the analysis necessary in the context of mandated disclaimers. Specifically, the Supreme Court's analysis of the disclaimer requirement imposed by the state in Zauderer still included an evaluation of whether the speech at issue was inherently or potentially misleading. Based on the specific facts in Zauderer, involving attorney advertising and the public's understanding of the difference between "fees" and "costs," the Supreme Court determined that the state's assumption that the speech at issue was potentially misleading was "hardly a speculative one" going so far as to say that the possibility for deception was "self-evident." Zauderer, 471 U.S. at 652-53.⁶

The Supreme Court's decision in Ibanez v. Florida Dept. of Business and Prof. Regulation, Board of Accountancy, 512 U.S. 136 (1994), decided after Zauderer, reinforces the fact that the court must do an analysis of whether the restricted speech is false or misleading. Ibanez involved a challenge to a decision by the Florida Board of Accountancy reprimanding an attorney for including her "CFP" (Certified Financial Planner) designation in advertising for her law practice. Id. at 138. One argument presented by the Board in that case was that the reprimand was appropriate because the advertising was "potentially misleading," entitling the Board to enact measures short of a total ban to prevent deception or confusion (*i.e.*, require a disclaimer). Id. at 146. The Supreme Court rejected the Board's disclaimer argument stating:

⁶ Prior to Zauderer, the Supreme Court had a long history of evaluating cases dealing with attorney advertising. See Bates v. State Bar of Arizona, 433 U.S. 350 (1977); In re R.M.J., 455 U.S. 191; Ohralik v. Ohio State Bar Assn', 436 U.S. 447 (1978). This history clearly made the Court in Zauderer more comfortable in reaching the conclusion that it was self-evident that the speech at issue was misleading. Zauderer, 471 U.S. at 652-53.

If the “protections afforded commercial speech are to retain their force,” Zauderer, 471 U.S., at 648-649, 105 S. Ct., at 2280-2281, *we cannot allow rote invocation of the words “potentially misleading” to supplant the Board’s burden to “demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.”* Edenfield, 507 U.S., at 771, 113 S. Ct., at 1800. ...

Given the state of this record – the failure of the Board to point to any harm that is potentially real, not purely hypothetical – we are satisfied that the Board’s action is unjustified.

Ibanez, 512 U.S. at 146 (emphasis added).

The Ibanez decision is on all fours with the present case. Like the Board in Ibanez, the Director has not come forward with any concrete evidence to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree. Throughout his Opposition, the Director relies on nothing more than his bald assertion that the existing labeling practices are misleading, but without any supporting evidence, this amounts to nothing more than speculation. Ibanez unequivocally holds that such “rote invocation” of the word “misleading” – as the Director has done in this case – is insufficient to meet the state’s burden. Id.

In opposing OTA’s motion, the Director does not rebut the fact that he has not come forward with any concrete evidence, beyond his own belief, that the existing labeling practices are in fact misleading to consumers. Indeed, the only evidence that the Ohio Department of Agriculture had, prior to enacting the Rule, relates to what the Director dubbed a “food scare.” The Director testified that after Pennsylvania enacted a rule regulating rbST non-use labels, the Department received some calls from consumers asking the Department whether rbST was safe. The Director testified that the “[w]e did not want to create any sort of apprehension in the marketplace about the safety of the milk produced either with rbST or without rbST. In addition, we wanted to make sure – this was a new issue to many consumers – that they had the most accurate information available about the whole issue.” (Boggs Depo. at 22:9-23:2).

Thus the “evidence” the Department had that consumers were being misled had nothing to do with the non-use labels that had been on dairy products sold in Ohio for over a decade, and instead to do with some questions the Department received about a particular product because of

a regulation that was passed in another state. Nothing in the Opposition or Boggs' testimony provides concrete evidence that consumers were being misled or even that they could potentially be misled.

Jones also testified that there were no consumer complaints about dairy labeling prior to enactment of the Rule. In his deposition Jones testified as follows:

Q: And are you sure that you have e-mails prior to October 22nd of '07 that commented adversely about rbST labeling on milk products?

A: I can't say that I'm sure of that. I didn't make a date as to when they started, but we had very few – very few, if any, really –

Q: It's possible you had none before October 22nd of '07; is that correct?

A: Possibly we had not. That's possible yes.

Q: And if you had any –

A: We would have ... We would have produced them, yes.

(Jones Depo at 9:20-10:12). In fact, no documents were produced to OTA indicating that there have been any consumer complaints about labels prior to enactment of the Rule.

Jones testified further that there were no surveys or analyses conducted to determine whether consumers were misled by the dairy labels because, according to Jones, the Department "did not have time." (Jones Depo. at 37:5-6). When confronted with the over 2500 e-mails in opposition to the Ohio Rule, Jones testified, incredibly, that those e-mails were actually evidence that consumers were misled, because, according to him, it showed they did not understand the Rule. (Jones Depo. at 37:1-38:1) ("Q: But I thought the reason for the rule was because consumers were misled? Why didn't you conduct an analysis of whether they were misled? A: We did not have time. 2700 e-mails were enough to tell us that they were misled."). When asked how the Department determined that consumers had been misled Jones testified that in addition to the e-mails in opposition to the Rule "[i]t was a general conclusion from the meetings that we had discussing the hearings and listening sessions. Q: Conclusions by whom? A: By ODA staff." (Jones Depo. at 39:9-19).

It is clear from the testimony of Boggs and Jones that ODA did not rely on any evidence that consumers had been or could potentially be misled. Rather the ODA inferred that the labels were false and misleading based on e-mails in opposition to the proposed rule and comments

from dairy industry insiders, many with a significant financial stake in the outcome of the rulemaking process. Such unsupported inferences *can not* form the basis of an infringement on plaintiff's members' constitutional free speech rights.

Faced with the utter lack of evidence, documentary or otherwise, of actual consumer confusion, the Director is forced to argue that the relevant standard is only whether the regulation is "reasonably related" to preventing consumers from being misled and does not require him to come forward with evidence that consumers have, in fact, been misled or could potentially be misled. However the weight of authority is clear that, to pass muster under the First Amendment, the state has the burden to demonstrate that the commercial speech at issue is, at a minimum, potentially misleading such that a disclaimer is necessary to prevent any potential for deception of consumers. Ibanez, 512 U.S. at 146; Mason v. Florida Bar, 208 F.3d 952, 958 (11th Cir. 2000). In this case, the Director has fallen well short of that burden.

ii. The Director Has Failed to Satisfy the Three-Prong Central Hudson Test

The Director argues that the Zauderer "reasonableness" test exempts the Director from being required to demonstrate that the Ohio Rule: (1) achieves a substantial government interest; (2) directly and materially advances that interest; and (3) is no more extensive than necessary to serve that interest. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557, 566 (1980). Instead, the Director argues that he need only show that the FDA-disclosure statement is "reasonably related to Ohio's bona fide interest in preventing consumers from being misled regarding the products they consume." As established above, the Director cannot even meet this standard because there is no evidence that consumers have been or potentially will be misled – in short the Director has presented no interest for which the Ohio Rule could possibly be reasonably related to. In any event, the standard relied upon by the Director is not the correct standard to be applied in this case. The Court in Ibanez makes clear that even where the issue is mandatory disclosure requirements, the state is still subject to the multi-prong Central Hudson test.

The Director relies on the Second Circuit's decision in National Electrical Manufacturers Assoc. v. Sorrell, 272 F.3d 104 (2nd Cir. 2001) for the position that the "reasonable relationship" test under Zauderer is the applicable standard for evaluating state mandated disclosures under the First Amendment. (Opposition at 9). However the Sorrell court's characterization of Zauderer, as articulated by the Director, is belied by the Supreme Court's decision in Ibanez that disclosure requirements are indeed subject to the multi-prong test first set out in Central Hudson. Indeed, the court in Sorrell at least satisfied itself that the requirement that the state interest is substantial was met finding that "Vermont's interest in protecting human health...is a legitimate and substantial interest."

While the Director interprets the Second Circuit as suggesting that the multi-prong test in Central Hudson does not apply to disclosure requirements, other circuits have been clear in finding that, as in Ibanez, the Central Hudson test applies to disclosure requirements. The Eleventh Circuit in Mason, 208 F.3d 952, applied the Central Hudson factors to a requirement that an attorney provide a disclaimer to his advertisement explaining the meaning of the AV rating in Martindale-Hubbell. See also Borgner v. Brooks, 284 F.3d 1204, 1206-07 (11th Cir. 2002), cer't denied, 537 U.S. 1080 (applying all of the Central Hudson factors to a state requirement that dentists include disclaimers to prevent potential consumer confusion); Commodity Trend Service, Inc. v. Commodity Futures Trading Commission, 233 F.3d 981, 994 (7th Cir. 2000) (same). Indeed, the Circuit Court cases that have addressed this issue, apply the "reasonable relationship" test used in Sorrell as the final prong of the Central Hudson test, where the court must determine whether there exists a reasonable fit between the government's goals and the means chosen to accomplish it. Mason, 208 F.3d at 955-56 (The Central Hudson test inquires into "whether the extent of the restriction on protected speech is in reasonable proportion to the interests served.").

The facts in Mason are closely analogous to the present case. In Mason, the state bar justified its disclosure requirement by stating that it had an interest in ensuring the public had access to relevant information to assist in the comparison and selection of attorneys. Mason, 208 F.3d at 956. This position is akin to the Director's statement that the disclaimer is necessary to

provide consumers with relevant information to ensure that when purchasing milk, the consumer is not misled into thinking that milk from non-rbST treated cows is superior to other milk.

(Opposition at 16). Much like the Director here, in Mason the state bar failed to produce any concrete evidence of identifiable harm other than unsupported speculation. The Mason court rejected the argument of the state bar that the restriction should be upheld because it merely required the use of a disclaimer stating:

Even partial restrictions on commercial speech must be supported by a showing of some identifiable harm. Accordingly, *we hold that the Bar is not relieved of its burden to identify a genuine threat of danger simply because it requires a disclaimer, rather than a complete ban on Mason's speech.*

Mason, 208 F.3d at 958 (emphasis added).

The Ibanez decision provides this Court with a clear direction that even in the context of mandatory disclaimer requirements, the Director still has the burden to demonstrate that the harms it recites are real and that the disclaimer requirement will in fact alleviate them to a material degree. See Ibanez, 512 U.S. at 146 (quoting Edenfield v. Fane, 507 U.S. 761, 771 (1990)). The Director has made no attempt to meet this burden, relying instead on an untenable legal argument that in effect seeks to do an end run around his burden. The Director must still establish each of the three Central Hudson factors to justify regulating the commercial free speech of plaintiff's members.

a. The Restriction Does Not Achieve a Substantial Governmental Interest

OTA does not quarrel with the Director's assertion that Ohio has a substantial interest in ensuring the accuracy of consumer information and from preventing consumers from being misled regarding the products they consume. However, the Director must do more than just show that it has a substantial interest; it must also demonstrate that the Rule *achieves* that substantial government interest. Central Hudson, 447 U.S. at 566. The Director has entirely failed to meet his burden. The Director has not shown, with respect to either composition or production claims, that the labels used by many of OTA's members are false and misleading. The Director cannot pass the first hurdle under the Central Hudson test by relying solely on the

prevention of misleading commercial speech if the commercial speech at issue is not even potentially misleading.

b. The Restriction Does Not Directly and Materially Advance the State Interest

Central Hudson requires the Director to show that the Ohio Rule directly and materially advances the state interest. The Director, under this prong, must “demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.” Edenfield, 507 U.S. at 770-771. The Director “must come forward with some quantum of evidence, beyond its own belief in the necessity for the regulation, that the harms it seeks to remedy are concrete and that its regulatory regime advances the stated goals.” Pagan v. Fruchey, 492 F.3d 766, 771 (6th Cir. 2007).

In support of this prong the Director asserts that the restriction on composition claims is warranted to restrict “only those claims which are false and misleading.” But, as was shown above, for organic companies, those composition claims are neither false nor misleading and the Director has provided no evidence to the contrary. The Director asserts that for production claims the Rule advances the state’s interest by requiring the “disclosure of a truthful statement referencing the pertinent findings by the FDA that effectively removes the *possibility* that consumers will be misled ...” (Opposition at 16). Requiring the disclosure of even “truthful” statements, however, is unconstitutional where, as here, the Director has failed to provide any evidence that the disclosure statement directly and materially advances the state’s interests in preventing consumers from being misled. Because the Director has failed to provide any evidence that consumers were misled in the first place, he has failed to meet his burden.

c. There is Not a Reasonable Fit Between the Government’s Goals and the Means Chosen to Accomplish Them

The final prong of the Central Hudson test requires that the Court determine whether there is a “reasonable fit” between the government’s goals and the means chosen to accomplish

them – a means that is “narrowly tailored” to achieve the desired objective. Lorillard Tobacco v. Reilly, 533 U.S. 525, 556 (2001).

Director Boggs’ own testimony establishes that there were “obvious less-burdensome alternatives” to the Rule ultimately enacted by the Director. Florida Bar v. Went For It, Inc., 515 U.S. 618, 632 (1995). Boggs testified that under the previously existing FDA guidance, Ohio could regulate labels it deemed false and misleading.

Q: Isn’t it correct, sir, that prior to the establishment of the rule, the Ohio rule that’s at issue in this lawsuit ODA had the power to regulate the Smith dairy labeling rule under the FDA guidance.

A: Yes. Under the FDA guidance, I was aware that we had the ability to enforce the guidance.

(Boggs Depo. at 29:23-30:12).

Moreover, Boggs testified that the Ohio Rule was stronger than the FDA guidance, but has yet to provide an answer as to *why* Ohio imposed the stricter rule.

Q: Isn’t the [Ohio Rule] stronger than the FDA guidance?

A: It is my belief that it is stronger than the FDA guidance, as the guidance says, “States should evaluate any labeling statement about rbST in the context of the complete label and do what they think is necessary.”

(Boggs Depo. at 35:16-22).

Jones’ testimony on this point is even more telling:

Q: Did the advisory committee⁷ make a recommendation [as to what the proposed rule would require]?

A: Not an official recommendation ... *most of them wanted us to follow the interim guidance*, which if you look at our final rule, it’s almost identical to the interim guidance that was written back in 1994.

Q: If it was identical, then why did you need it?

⁷ The composition of the advisory committee was, according to the Director, intended to include members of all parts of the dairy industry; however, no large organic processor was informed by the Department of the existence of the advisory committee. Instead, at least three members had direct links to the Monsanto corporation.

A: Oh, *we had to make some clarifications*. For one thing, it – because it said the interim guidance said that the states shall issue their regulatory – in other words, they left it up to the states to define the regulatory action.

Q: But you adopted a rule that actually is more strict than the interim guidance, right?

A: Might be a little...

(Jones Depo at 50:9-51:2) (emphasis added).

There is no doubt that Ohio is entitled to regulate commercial speech; however, Ohio must show that there is a reasonable fit between the means selected and the Director's stated goals. That is obviously not the case here. Jones testified that the FDA guidance needed to be "clarified" to ensure that Ohio could enforce the guidance. Such clarification, however, was clearly unnecessary; the record is replete with evidence of states that have chosen to pass laws regulating dairy labels which are much less restrictive than Ohio's rule. (See International Dairy Foods Association's Motion for Summary Judgment at 37-38). In fact, the Pennsylvania rule, which was admittedly the catalyst for the Ohio Rule, is less restrictive than the Ohio Rule *and* properly excludes the organic industry from its reach. (See Pennsylvania Code § 59.21). The Director has articulated no justification, nor can he, for why the restrictive Ohio Rule was enacted.⁸

⁸ The Director articulated four "objectives" that the Ohio Rule is purportedly "narrowly tailored to meet." (Opposition at 16). Those objectives were (1) that the Rule provides a "reasonable mechanism to convey" information regarding the absence of rbST "in a manner as to ensure the message will not be misleading"; (2) that the Rule does not prohibit all composition claims, rather it only restricts those that are either false and misleading; (3) that the Rule does not require the processor to attest to or "second" the FDA's findings; and (4) that the Rule is easy to comply with because the disclaimer language can be half the size of the permitted claim. Each of these "objectives" have been addressed above. The Rule has been shown to be not based on any actual consumer confusion, highly restrictive and unsuitable for the organic industry. These "objectives" are little more than red herrings, designed to distract the Court from the undisputable fact that no consumers have been misled by the dairy product labels that have been in use in Ohio for years.

C. The Ohio Rule is Unconstitutionally Void For Vagueness Because it Fails to Clearly Describe the Language it Prohibits and Provides Unbridled Discretion for Enforcement in the Ohio Department of Agriculture

The Director argues that Grayned v. City of Rockford, 408 U.S. 104 (1972), does not support OTA's position that the Ohio Rule is unconstitutionally void for vagueness because that case does not expressly consider whether the use of the word "may" in a statute renders it unconstitutional. Of course Grayned does not address every possible semantic construction capable of rendering a statute unconstitutional and OTA's motion does not argue that it does. Grayned supports OTA's argument because it provides the standard for determining whether a law is void for vagueness. Specifically, Grayned provides that a statute is unconstitutionally void for vagueness if its prohibitions are not clearly defined or if it delegates too much discretion in enforcement. *Id.* at 108-09.

Defendant's reliance on the Arizona court of appeal case, State v. Mutschler, 65 P.3d 469 (Ariz. App. 2003), is misplaced. In that case, the statute defined a prohibited "live sex act business" as "any business that in which one or more persons may view, or may participate in, a live sex act for consideration." Clearly, the use of the word "may" in the law challenged in Mutschler was intended to prohibit any business in which "it was possible to" (*i.e.*, in which someone may/can) watch or engage in sex for money. Unlike the Ohio Rule, the rule at issue in Mutschler, did not say that such business "may" be illegal.

By contrast, the Ohio Rule states that the use of particular language on a milk label (*e.g.*, no pesticides) "may" be false or misleading. Accordingly, the use of "may" in the Ohio Rule is with respect to whether particular label phrasing is a violation of the statute at all. The word "may" in the Ohio Rule, therefore, leaves enforcement of the statute (*i.e.*, the determination of whether particular language on a label is indeed false or misleading) up to the discretion of the Director, who can selectively enforce the statute against anyone he chooses. Boggs' deposition testimony bore this possibility out:

Q: ... If you look at (subsection) D, it says statements may be considered to be false or misleading. Do you see that?

A: Uh-huh.

- Q: Who would decide whether a particular statement would be considered false or misleading?
A: Ultimately, that would be my decision upon the advice of counsel and our dairy chief.

(Boggs Depo at 75:9-76:2).

The Director argues that “when a law is susceptible of more than one permissive construction, courts must ‘construe the [law] to avoid [constitutional] problems’ if it is ‘fairly possible.’” (Opposition at 42). Under the analytical approach proffered by the Director, no statute would ever be void for vagueness if it was possible to create a non-vague interpretation of the statute. Indeed, the language from the case quoted by the Director contains the following disclaimer: “There are limits to this principle, however. The canon of constitutional avoidance does not supplant traditional modes of statutory interpretation.” Boumediene v. Bush, 128 S.Ct. 2229, 2271 (2008).

The Director next argues that where public interests are involved, the word “may” actually means “shall.” The Director’s support for this novel proposition is a non-binding secondary source (the Corpus Juris Secundum). This argument is not supported by any relevant case law or even by basic common sense. Ordinary textual analysis, and reference to a dictionary definition of the word “may,” demonstrates that “may” does not have the same meaning as “will” or “shall.”

Finally, the Director does not address, in any manner, the cases cited in OTA’s motion for the proposition that courts apply heightened scrutiny when determining the constitutionality of potentially vague statutes that implicate First Amendment rights. The Director effectively concedes the point that, in the context of vague statutes which potentially implicate First Amendment rights “an enactment . . . may withstand facial constitutional scrutiny only if it incorporates a high level of definiteness.” Belle Maer Harbor v. Charter Township of Harrison, 170 F.3d 553, 557 (6th Cir. 1999).

D. The Ohio Rule Violates the Dormant Commerce Clause of the United States Constitution

The hardships imposed by the Ohio Rule are similar for both OTA’s and IDFA’s members. The arguments for why the Ohio Rule violates the dormant or negative Commerce

Clause of the United States Constitution are also similar. For purposes of brevity, OTA incorporates by reference the arguments made by IDFA in its Reply brief filed concurrently herewith and the declarations and Separate Statement of Undisputed Facts submitted by OTA in support of its Motion for Summary Judgment.

III. CONCLUSION

There can be little room for doubt that the Director has failed in his burden to prove that Ohio consumers have been or potentially could be misled by plaintiffs' members' labels. The labels at issue in this case have been used in Ohio for over a decade, with no incident. With no evidence of any harm to any consumer, the purported justifications for the Rule fall apart and reveal the Director's true motives, to protect Ohio processors who choose to use rbST and to further the interests of the company which distributes the drug. These justifications simply cannot support the infringement of plaintiffs' members' First Amendment rights and the burden on interstate commerce. Moreover, the Rule stands as a direct obstacle to the accomplishment of the Organic Foods Production Act's stated objectives and is impermissibly void for vagueness. For all of these reasons, OTA respectfully requests this Court grant OTA's motion for summary judgment.

DATED: September 16, 2008.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Organic Trade Association's Reply in Support of its Motion for Summary Judgment and in Opposition to Defendant's Motion for Summary Judgment** was filed electronically this 16th day of September, 2008 and that a copy will be served by first class U.S. mail upon any party not appearing on the Court's electronic service list.

/s/ Randall J. Sunshine
Randall J. Sunshine (CA Bar No. 137363)